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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,043	10/23/2000	Brita Sjoblom	1103326 0642	9139

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,043	HAULER ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 11-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend on another multiple dependant claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10, 12, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part d, recites the limitation, "other substances." This claim is considered to be vague and indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Appropriate correction is required.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation 60-95 weight percent, and the claim also recites "preferably 75-90 weight %" which is the narrower statement of the range/limitation. Appropriate correction is required.

Claim 12 states "the polymer is selected from the group consisting of..." What polymer is being referred to here? The polymer in the liquid medium? Or the polymer which can act as a dispersing agent? Appropriate clarification is required.

Claim 14 states, "liquid in which polymer is soluble..." However, claims 7 and 9 teach a suspension and an emulsion, respectively Therefore it is not required that the polymer be soluble, and there is improper antecedent basis for this limitation. Appropriate correction is required.

Claim 15 recites the limitation "cold medium" in any of the preceding claims. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,017,383 to Ozawa *et al.*. Ozawa *et al.* teach a method of producing a fine coated pharmaceutical preparation (abstract). More specifically, Ozawa *et al.* teach forming liquid droplets by dissolving or suspending a drug and a binder into a liquid medium (c 2, l 9-13). Ozawa *et al.* teach that the drug can be any drug (c 2, l 14-16), the binder can be chosen from a broad range of choices, including cellulose derivates (c 2, l 38-59), and the liquid medium can be chosen from methanol, ethanol, water, methylene chloride, and mixtures thereof (c 2, l 63 – c 3, l 9). Additionally, Ozawa *et al.* teach that the binder can be between 1-30 parts by weight per 100 parts of the drug (c 2, l 59-62). Further, Ozawa *et al.* teach that the resulting droplets are made by an ordinary spray method, and that the use of an atomizer is convenient (c 3, l 29-35). Lastly, Ozawa *et al.* teach that the liquid medium is removed from the coated particles through various known methods, such as drying (c 5, l 3-7).

Additionally, claims 18 and 19 are also anticipated by Ozawa et al. Claims 18 and 19 are product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process,

determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Therefore, Ozawa *et al.* anticipate claim 18 by teaching a microparticle, and anticipates claim 19 by teaching a coated microparticle. Therefore, the teachings of Ozawa *et al.* anticipate applicant's instant claims.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by GB 2329124 to Ratwatte. Ratwatte teaches a method a producing agent forms by dispersing an agent composition in a solution of a coating material in a liquid carrier material and spraying the resultant dispersed mixture to form fine droplets which are frozen, then drying the said frozen particles to produce a plurality of individual solid parties comprising the agent composition coating with the coating material. Ratwatte further teach that the agent material can be a bio-pharmaceutical or another agent, such as a vitamin (abstract).

It is the position of the examiner that the agent composition of Ratwatte reads on applicant's pharmaceutically active substance (1a). Further, the coating material of Ratwatte reads on applicant's polymer (1b). Next, the liquid carrier material of Ratwatte reads on applicant's claimed liquid in which the pharmaceutically active substance and polymer are suspended, dissolved, or emulsified (1c). Lastly, Ratwatte teaches

spraying the above mixture to form droplets, followed by drying the droplets to form solid particles. It is the position of the examiner that this process anticipates applicant's independent claim 1.

Additionally, claims 18 and 19 are also anticipated by Ratwatte. Claims 18 and 19 are product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Therefore, Ratwatte anticipates claim 18 by teaching a microparticle, and anticipates claim 19 by teaching a coated microparticle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozawa *et al.*, as discussed above, and in view of the following comments. Ozawa *et al.* is discussed above as teaching a method for making particles which is identical to the

process claimed by applicant. However, Ozawa *et al.* does not state the percentages of specific components in terms of dry weight percents. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Additionally, the reference does not specifically teach that the drying of the particles must occur by freeze drying. However, the reference does teach that any well known pharmaceutical drying method can be employed. It is the position of the examiner that one of ordinary skill in the pharmaceutical art would use freeze drying as the ultimate step in the Ozawa *et al.* process, in order to dry the droplets and create homogenous microparticles. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratwatte, as discussed above, and in view of the following comments. Ratwatte is discussed above as disclosing applicant's method of combining a drug, a coating and a

liquid carrier, which is spray dried to form droplets, then freezes dried to form microparticles.

First, Ratwatte does not specifically teach (in the available abstract) applicant's specifically claimed polymers. However, it is well known in the pharmaceutical art that the polymers claimed by applicant in instant claim 12 are regularly used as coating components. Therefore, one of ordinary skill in the art would have been motivated to use a well known coating polymer where Ratwatte calls for a "coating material." Additionally, the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Second, Ratwatte does not give specific percentages of the individual components of the composition. However, this is not to say that Ratwatte's composition does not teach applicant's instantly claimed amounts. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Third, Ratwatte does not specify (in the available abstract) the specific solvent claimed by applicant. Again though, the solvents claimed by applicant are well known solvents in pharmaceutical compositions, and the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

It is the position of the examiner that the method of making microparticles disclosed by Ratwatte clearly suggests the method of making microparticles which is instantly claimed by applicant. The burden has been shifted to applicant to disclose any differences between the two processes. Furthermore, one of ordinary skill in the art would have been motivated to form pharmaceutical particles based on the teachings of Ratwatte. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
December 13, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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